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MAR - 7 2001

Mr. Ira Goldberg
President
Planetary Formulas
Soquel, California 95073

Dear Mr. Goldberg:

This is in response to your letter of December 8, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Planetary Formulas, is making the following claim, among others, for the product **Guggal Cholesterol Compound**:

“...help maintain cholesterol levels within a normal range.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA150

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp:02/12/01:docname:74386a:disc2

December 8, 2000

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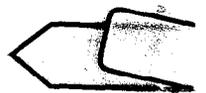
Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C st. SW., Washington, D.C. 20204

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Guggal Cholesterol Compound, Planetary Formulas is a manufacturer of Guggal Cholesterol Compound.

Statements being made in the labeling of Guggal Cholesterol Compound:

- (1) Ayurvedic botanical to (help maintain cholesterol levels within a normal range.)
- (2) Guggal Cholesterol Compound utilizes a guggal extract rich guggalsterones, compounded in the traditional manner to capture guggal's vast array of essential constituents.



To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. Planetary Formulas possesses substantiation that the statements are truthful and not misleading.


Ira L. Goldberg
President, Planetary Formulas

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